Introduced by Senator Corbett

February 21, 2007

An act to add Article 4.5 (commencing with Section 4079) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 472, as amended, Corbett. Prescription drugs: labeling requirements *and panel*.

Existing law, the Pharmacy Law, provides for the licensing and regulation of the practice of pharmacy by the California State Board of Pharmacy in the Department of Consumer Affairs. Existing law prohibits a pharmacist from dispensing a prescription, except in a container that meets certain labeling requirements.

This bill would declare the intent of the Legislature to adopt establish a prescription drug label panel in conjunction with the California State Board of Pharmacy, for purposes of adopting and implementing a standard format for the labeling of prescription drug containers dispensed in the state, that would include regulations for the font size of printed words on the label and on the placement of information of the prescription and would provide that translated prescription drug labels should be made available to the patient if the patient's primary language is not English, as specified. The bill would require the adoption of those standards by September 30, 2008, and would require in-state pharmacies to begin using the standardized labels on January 1, 2009.

Because a knowing violation of the Pharmacy Law constitutes a crime, and because the above-described provisions would impose additional

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duties under that law, this bill would impose a crime and state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: no ves. State-mandated local program: no-yes.

The people of the State of California do enact as follows:

- SECTION 1. The Legislature hereby finds and declares all of 2 the following:
 - (a) Health care costs and spending in California are rising dramatically and are expected to continue to increase.
- (b) In California, prescription drug spending totaled over \$188 5 6 billion in 2004, a \$14 billion dollar per year spending increase since 1984. 7
 - (c) Prescription drug cost continues to be among the most significant cost factors in California's overall spending on health care.
 - (d) According to the Institution of Medicine of the National Academies, medication errors are among the most common medical errors, harming at least 1.5 million people every year.
 - (e) Up to one-half of all medications are taken incorrectly or mixed with other medications that cause dangerous reactions that can lead to injury and death.
 - (f) Approximately 46 percent of American adults cannot understand the label on their prescription medications.
 - (g) Ninety percent of Medicare patients take medications for chronic conditions and nearly one-half of them take five or more different medications.
 - (h) It is the intention of the Legislature to adopt a standard format for the labeling of prescription drug containers dispensed in the state. That would include regulations for the font size of printed words on the label and the placement of information of the prescription and would provide that translated prescription drug

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labels should be made available to the patient if the patient's primary language is not English.

SEC. 2. Article 4.5 (commencing with Section 4079) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 4.5. Prescription Drug Label Panel

- 4079. (a) (1) A prescription drug label panel is hereby established, which membership shall be appointed to work with the board pursuant to subdivision (b). Five members shall be appointed by the Speaker of the Assembly, five members by the President pro Tempore of the Senate, and five members by the Governor. A majority of those appointees shall be from groups representing seniors and groups representing those with special issues regarding language and cultural competency in the use of prescription drugs.
- (2) In order to staff the panel for purposes of subdivision (b), the board may delegate all its functions under this article to its staff.
- (b) (1) The panel shall advise the board as to the development of a standardized label for prescription drug containers dispensed in this state.
- (2) The label shall be developed so that it does all of the following:
 - (A) It is readable for prescription drug users.
- (B) It describes the contents of the container so that prescription drug users with a 4th grade reading level can understand it.
- (C) It displays necessary information about properly taking the containers' contents so that prescription drug users with a 4th grade reading level can understand it.
- (D) It displays mandated warnings about the containers' contents so that prescription drug users with a 4th grade reading level can understand it.
- (E) A translation or interpretation of the directions for use can be obtained at the pharmacy dispensing the drug.
- (3) The panel shall also ensure in its recommendations that the implementation of the standardized label is affordable for independent pharmacies.

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(c) (1) The panel shall be established and begin meeting on and after January 1, 2008.

- (2) After considering the recommendations of the panel, the board shall adopt a standardized label pursuant to subdivision (b) on or before September 30, 2008, and shall report to the appropriate committees of the Legislature on that date.
- (3) All in-state pharmacies shall begin using the standardized label on and after January 1, 2009.
- 8 9 SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because 10 the only costs that may be incurred by a local agency or school 11 district will be incurred because this act creates a new crime or 12 infraction, eliminates a crime or infraction, or changes the penalty 13 for a crime or infraction, within the meaning of Section 17556 of 14 15 the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIIIB of the California 16 17 Constitution.